

# **EXHIBIT A**

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*Attorneys for Plaintiffs*

**IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA**  
**FOR THE COUNTY OF KERN**

ASHLEY VICKERS, Individually, and D.H., a  
 minor child by and through a guardian ad litem,  
 Ashley Vickers,

*Plaintiffs,*

v.

MEAD JOHNSON & COMPANY, LLC,  
 MEAD JOHNSON NUTRITION COMPANY,  
 ABBOTT LABORATORIES, DIGNITY  
 HEALTH D/B/A BAKERSFIELD MEMORIAL  
 HOSPITAL, CHILDREN'S HOSPITAL LOS  
 ANGELES, and DOES 1-10, inclusive,

*Defendants.*

Case No. BCV-22-100810

**COMPLAINT FOR DAMAGES AND  
 DEMAND FOR JURY TRIAL**

- (1) Strict products liability for design defect
- (2) Strict products liability for failure to warn
- (3) Negligence
- (4) Intentional misrepresentation
- (5) Negligent misrepresentation
- (6) Negligent failure to warn

1 Plaintiffs bring this Complaint and Demand for Jury Trial (the “Complaint”) against Mead  
2 Johnson & Company, LLC, Mead Johnson Nutrition Company, and Abbott Laboratories,  
3 (collectively “the Defendant Manufacturers”), and Dignity Health d/b/a Bakersfield Memorial  
4 Hospital (“Dignity”), and Children’s Hospital Los Angeles (collectively “The Hospitals”), together  
5 “Defendants.” Plaintiffs allege the following upon personal knowledge as to Plaintiffs’ own acts and  
6 experiences and upon information and belief, including investigation conducted by Plaintiffs’  
7 attorneys, as to all other matters.

## 8 I. INTRODUCTION

9 1. This action arises out of the injuries suffered by premature infants (collectively, the “Injured  
10 Infants”) who were given the Defendant Manufacturers’ cow’s milk-based infant feeding products at  
11 the Hospitals. The Hospitals acquired and supplied the Defendant Manufacturers’ products to the  
12 Injured Infants and negligently failed to warn of their unreasonably dangerous properties in a  
13 reasonable manner. This caused the Injured Infants to develop necrotizing enterocolitis (“NEC”), a  
14 life-altering and potentially deadly disease that largely affects premature babies who are given cow’s  
15 milk-based feeding products. As a result, the Injured Infants were seriously injured, resulting in their  
16 death or long-term health effects and accompanying harm to their parents (collectively “Plaintiff  
17 Parents”).

18 2. Plaintiffs bring these causes of action against Defendants to recover for injuries that are the  
19 direct and proximate result of the Injured Infants’ consumption of the Defendant Manufacturers’  
20 unreasonably dangerous cow’s milk-based infant feeding products, which were acquired and supplied  
21 without adequate warning to the Injured Infants by the Bakersfield Memorial Hospital and Children’s  
22 Hospital Los Angeles.

## 23 II. PARTIES

24 3. Plaintiff Ashley Vickers is a natural person and a resident of the State of California. Ms.  
25 Vickers is the mother of D.H., a minor.

26 4. Plaintiff D.H. is a natural person and a resident of the State of California. D.H. is a minor  
27 child of Ashley Vickers.

5. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, “Mead”) are manufacturers of cow’s milk-based infant feeding products and market many of these products under the “Enfamil” brand name.

6. Defendant Abbott Laboratories (“Abbott”) is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow’s milk-based infant feeding products and markets many of its products under the “Similac” brand name.

7. Defendant Bakersfield Memorial Hospital is a corporation incorporated under the laws of the State of California. Its principal place of business is in California.

8. Defendant Children’s Hospital Los Angeles is a corporation incorporated under the laws of the State of California. Its principal place of business is in California.

### III. JURISDICTION AND VENUE

9. This Court has jurisdiction in this matter pursuant to California Code of Civil Procedure § 410.10. Defendants conduct authorized business in the State of California. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this State. This suit arises out of Defendants’ forum-related activities, such that the Superior Court’s exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

10. Venue is proper pursuant to California Code of Civil Procedure § 395.5 because Defendants Bakersfield Memorial Hospital has its principal place of business in Bakersfield County.

11. This action is an unlimited civil case because the amount of damages requested exceeds \$25,000 and because none of the Plaintiffs’ causes of action meet the criteria for limited civil cases in the California Code of Civil Procedure.

### IV. FACTUAL ALLEGATIONS

#### *D.H.’s NEC Diagnosis*



12. D.H. was born prematurely at Bakersfield Memorial Hospital in Bakersfield, California on November 2, 2021.

13. D.H. was fed Similac and/or Enfamil cow's milk-based products by staff at the Hospitals from shortly after his birth.

14. Shortly after D.H. first ingested the Defendant Manufacturers' products, he developed NEC.

15. D.H. was forced to stay in the NICU longer, treated with antibiotics and Occupational Therapy and has continued to suffer long term health issues.

***Cow's Milk-Based Feeding Products Are Known to Cause NEC***

16. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

17. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

18. For example, in one randomized, multicenter study of 926 preterm infants, NEC was six to ten times more common in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and three times more common in babies who received a combination of formula and breast milk. For babies born at more than 30 weeks gestation, NEC was 20 times more common in those only fed cow's milk formula than in those fed breast milk.

19. Another randomized controlled trial showed that preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC (NEC that requires surgical treatment), compared to preterm babies fed a diet that included some cow's milk-based products.

20. Yet another study that analyzed the data from a 12-center randomized trial concluded that fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of

1 NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast  
2 milk-based fortifier.

3 21. A Surgeon General report, The Surgeon General's Call to Action to Support Breastfeeding,  
4 warns that, "for vulnerable premature infants, formula feeding is associated with higher rates of  
5 necrotizing enterocolitis." The report also states that premature infants who are not breastfed are  
6 138% more likely to develop NEC.

7 22. The American Academy of Pediatrics, "an organization of 67,000 pediatricians committed to  
8 the optimal physical, mental, and social health and well-being for all infants, children, adolescents,  
9 and young adults," has advised that all premature infants should be fed either their mother's milk or,  
10 if their mother's milk is unavailable, pasteurized human donor milk. This recommendation is based  
11 on the "potent benefits of human milk," including "lower rates of . . . NEC."

12 23. A multicenter, randomized, controlled trial found that premature and low-birth-weight infants  
13 fed an exclusive breast milk-based diet suffered NEC only 3% of the time while premature and low-  
14 birth-weight infants receiving cow's milk-based formula suffered NEC 21% of the time.

15 24. Another study conducted a randomized comparison of extremely preterm infants who were  
16 given either (a) a diet of breast milk fortified with a breast milk-based fortifier or (b) a diet containing  
17 variable amounts of cow's milk-based products. The babies given exclusively breast milk products  
18 suffered NEC 5% of the time. The babies given cow's milk products suffered NEC 17% of the time.

19 ***Safer, Nutritionally Superior Alternatives To Cow's Milk-Based Products Exist***

20 25. A range of options are available that allow preterm and low-birth-weight infants to be fed  
21 exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an  
22 established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover,  
23 hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

24 26. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition  
25 necessary to support premature and low-birth-weight infants without the elevated risk of NEC  
26 associated with cow's milk-based products. For example, in a study analyzing preterm infants who  
27 were fed an exclusive breast milk-based diet until they reached 34 weeks, all 104 infants exceeded  
28 standard growth targets and met length and head-circumference growth targets, demonstrating that



1 infants can achieve and mostly exceed targeted growth standards when receiving an exclusive breast  
2 milk-based diet. This is particularly true given the ability of breast milk-based fortifiers to provide  
3 the additional nutritional supplements necessary for adequate growth while receiving the protective  
4 benefits of a breast milk diet.

5 27. The Defendant Manufacturers' products not only pose a threat to infants' health, but also  
6 displace the breast milk they could otherwise receive. This displacement only increases infants'  
7 vulnerability to NEC, as studies show that breast milk protects against the disease. For example, a  
8 study analyzing 1,587 infants across multiple institutions concluded that an exclusive breast milk-  
9 based diet is associated with significant benefits for extremely premature infants and that it produced  
10 no feeding-related adverse outcomes.

11 28. For the above reasons, experts acknowledge that breast milk is the best source of nutrition for  
12 preterm infants and those at risk for NEC. Breast milk-based nutrition nourishes infants while  
13 creating a significantly lower risk of NEC.

14 29. At the time the Injured Infants were fed the Defendant Manufacturers' products, the science  
15 clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood  
16 that a baby will develop NEC, leading to severe injury and often death.

17 30. Despite the scientific consensus that the Defendant Manufacturers' cow's milk-based products  
18 present a dire threat to the health and development of preterm infants, the Defendant Manufacturers  
19 have made no changes to their products or the products' packaging, guidelines, instructions, or  
20 warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition,  
21 they incentivize hospitals that know the risks to use their products by providing them to the hospital  
22 for free or at a significant discount, in order that vulnerable infants and their families will become  
23 accustomed to using their products before discharge.

24 ***The Defendant Manufacturers' False And Misleading Marketing***  
25 ***Regarding Cow's Milk-Based Infant Products***

26 31. Abbott and Mead have aggressively marketed their cow's milk-based products as medically  
27 endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infants  
28 births.

1 32. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants  
2 while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk  
3 formulas and fortifiers are necessary for the growth and development of their vulnerable children.  
4 Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's  
5 supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their  
6 promotional websites, reference the science showing how significantly their products increase the  
7 risk of NEC.

8 33. Numerous studies have shown the detrimental impact of formula advertising on the rates of  
9 initiation and continuation of breastfeeding, including studies that show that as "hand feeding" (non-  
10 breastfeeding) advertisements increase, reported breastfeeding rates decrease in the following year.

11 34. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along  
12 with other formula manufacturers, are willing to spend massive sums to disseminate their message,  
13 with one study estimating that formula manufacturers collectively spent \$4.48 billion on marketing  
14 and promotion in 2014 alone.

15 35. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health  
16 Assembly—the decision-making body of the World Health Organization—developed the  
17 International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies  
18 to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing  
19 partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also  
20 forbade advertising or other forms of promotion of formula to the general public as well as providing  
21 sample products to mothers or members of their families.

22 36. While Abbott and Mead acknowledge the Code on their websites and claim to support the  
23 effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service.  
24 Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—  
25 that the nutrition they are supplying to their child will not provide the best chance of survival—while  
26 wholly failing to warn that their products come with a significantly increased risk of NEC.

27 37. For example, Abbott's website, on a page titled "Infant Formula Marketing," states: "We  
28 agree with the World Health Organization that breastfeeding provides the best nutrition for babies,



1 and we support its goal to increase breastfeeding. We also recognize that for infants who aren't  
2 breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe alternative  
3 to meet babies' nutritional needs." This statement ignores the existence of donor milk, as well as  
4 human milk-based formula.

5 38. Abbott markets and sells multiple products specifically targeting preterm and low-birth-  
6 weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers,  
7 Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac  
8 Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to  
9 assist underdeveloped babies in reaching their growth targets. For example, on the since-edited  
10 webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9  
11 months in the womb, so her body is working hard to catch up. During her first full year, feed her  
12 Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help  
13 support her development." Yet, no mention was made of the accompanying significantly increased  
14 risk of NEC. At some point, the website was edited to remove this statement. However, upon  
15 information and belief, the statement remained on the website until at least December 2020.

16 39. Mead markets and sells multiple products specifically targeting premature infants, including  
17 Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein,  
18 Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with  
19 Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and  
20 Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead  
21 emphasizes the purported similarities between its formula and breast milk, while failing to include  
22 any information about the nutritional deficits and dangers that accompany formula use. For example,  
23 the since-edited webpage for Enfamil Enfacare stated: "Premature babies fed Enfamil® formulas  
24 during the first year have achieved catch-up growth similar to that of full term, breastfed infants" and  
25 noted that Enfamil formulas include "expert-recommended levels of DHA and ARA (important fatty  
26 acids found naturally in breast milk) to support brain and eye development."

27 40. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is  
28 entirely focused on favorably comparing Enfamil's formula to breast milk, without any mention of

1 the product's extreme risks. Indeed, the terms "human milk" and "breast milk" are used 13 times in  
2 the advertisement, including in such statements as "for decades human milk has inspired the  
3 advancements in Enfamil formulas and now through extensive global research, we are taking an even  
4 closer look at human milk" and "only Enfamil NeuroPro has a fat blend of MFGM and DHA  
5 previously found only in breast milk." The webpage for the product has made similar manipulative  
6 claims, stating "Enfamil is backed by decades of breast milk research and multiple clinical studies"  
7 and it claims that "to create our best formulas, we collaborated on some of the most extensive breast  
8 milk studies to date[.]"

9 41. Formula manufacturers have long used their relationships with hospitals and the discharge  
10 process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost  
11 formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and  
12 even entire gift baskets to parents before their infants' discharge from the NICU or hospital.

13 42. Through this early targeting, the Defendant Manufacturers create brand loyalty under the  
14 guise of a "medical blessing," in hopes that new parents continue to use formula after they leave the  
15 hospital, resulting in increased expense for parents, significantly increased risk for babies, and  
16 increased profit for the Defendant Manufacturers. The Defendant Manufacturers' giveaways and gift  
17 baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by  
18 their healthcare professionals, and they have been shown to negatively impact breastfeeding rates.

19 43. Further, when the Defendant Manufacturers recognized a shift in the medical community  
20 towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called  
21 "Similac Human Milk Fortifier," and Mead developed "Enfamil Human Milk Fortifier." These  
22 names are misleading in that they suggest that the products are derived from breast milk, when, in  
23 fact, they are cow's milk-based products. One study, for example, found that only 8.8 percent of  
24 parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning a cow's milk-  
25 based product. The packaging appears as:





44. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers' cow's milk-based products to be a first choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infants.

#### ***The Defendant Manufacturers' Inadequate Warnings***

45. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.



1 46. The Enfamil products Mead markets specifically for premature infants are commercially  
2 available at retail locations and online. No prescription is necessary.

3 47. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the  
4 significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with  
5 Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide  
6 instructions or guidance for how to avoid NEC.

7 48. Mead cites no medical literature or research to guide the use of its products.

8 49. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of  
9 NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude  
10 of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

11 50. Mead deceived the public, parents, physicians, other medical professionals, and medical staff  
12 into believing that Enfamil products were a safe and necessary alternative, supplement and/or  
13 substitute to breast milk.

14 51. Despite knowing that its products were being fed to premature infants, often without the  
15 parents' informed consent, Mead failed to require or recommend that medical professionals inform  
16 parents of the significant risk of NEC or to require that parental consent be obtained prior to the  
17 products being fed to their babies.

18 52. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents  
19 believe that its products are safe and necessary for the growth of premature infants, despite the  
20 products in fact being extremely dangerous for premature infants. Abbott's products significantly  
21 increase the chances of a premature infant getting potentially fatal NEC.

22 53. The products Abbott markets specifically for premature infants are available at retail locations  
23 and online. No prescription is necessary.

24 54. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk  
25 of NEC (and resulting medical conditions, and/or death) associated with its products, or of the  
26 magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to  
27 avoid NEC.

28

1 55. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff  
2 into believing that its products were a safe and necessary alternative, supplement and/or substitute to  
3 breast milk.

4 56. Despite knowing that its products were being fed to premature infants, often without the  
5 parents' informed consent, Abbott failed to require or recommend that medical professionals inform  
6 parents of the significant risk of NEC or to require that parental consent be obtained prior to the  
7 products being fed to their babies.

8 ***Dignity's Failure to Warn***

9 57. On information and belief, Dignity was aware of the significantly increased risk of NEC and  
10 death associated with providing Abbott's and Mead's cow's milk-based products to its premature  
11 infant patients. Dignity knew or should have known that feeding these cow's milk-based products  
12 can cause NEC in premature infants who otherwise would not have developed this devastating  
13 condition. However, instead of warning of those dangers, or supplying breast milk-based feeding  
14 products to preterm infants like the Injured Infants, Dignity has continued to source, distribute, and  
15 supply the Defendant Manufacturers' products in its hospitals without any adequate warning of the  
16 attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities.

17 58. In fact, numerous Dignity medical facilities and hospitals throughout California purport to  
18 adhere to the tenets of the "Baby-Friendly Hospital Initiative," which seeks to increase rates of  
19 breastfeeding initiation, exclusivity, and diet duration. The "Baby-Friendly Hospital Initiative"  
20 specifically targets a reduction in the rates of necrotizing enterocolitis in preterm infants by  
21 encouraging implementation of exclusive breast milk diets among new mothers. Yet even though  
22 Dignity's birth facilities elsewhere in California have gained "Baby-Friendly Hospital" designation  
23 status, Bakersfield Memorial has not.

24 59. Dignity is and has been aware that human breastmilk provides significant health benefits to  
25 premature infants, including protection from disease and illness, such as NEC. Dignity, through its  
26 website and other materials, has expressly recognized that human breast milk is easier for infants to  
27 digest than cow's milk-based formula due to its biological properties, and that cow's milk-based  
28 formula is inferior to breastmilk because breastmilk "has many proteins that fight bacteria and viruses,



1 and may reduce . . . gastrointestinal diseases . . . while formula has no disease fighting or protective  
2 components.”

3 60. Although Dignity knew or should have known of the serious danger of the Defendant  
4 Manufacturers’ products, Dignity has continued to purchase, supply, and distribute these products to  
5 preterm infants without providing full and adequate warnings of the attendant risks to parents,  
6 healthcare professionals, and other medical staff at Bakersfield Memorial. As a result, the Injured  
7 Infants were fed the Defendant Manufacturers’ cow’s milk-based products at Bakersfield Memorial,  
8 causing their injuries. This occurred even though hospitals across the country, including Dignity’s  
9 own hospitals, warn and obtain consent from parents before providing other safer forms of nutrition,  
10 such as donor breast milk.

11 61. Dignity’s failure to warn of the risks posed by the Defendant Manufacturer’s products is  
12 entrenched (and compounded) by the financial benefits it accrues from its relationships with the  
13 Defendant Manufacturers. On information and belief, Dignity has received the Defendant  
14 Manufacturers’ cow’s milk-based products for free or at a significant discount and has granted their  
15 sales representatives have provided deceptive information that Dignity reasonably knew or should  
16 have known would ultimately reach parents through those staff. This arrangement dovetails with the  
17 Defendant Manufacturers’ own marketing strategy, which aims to “sell and service” healthcare  
18 professionals and medical staff as a means of converting them into “extra saalespersons.”

19  
20 ***Safer Alternative Designs***

21 62. The Defendant Manufacturers’ cow’s milk-based products made specifically for premature  
22 infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used  
23 pasteurized breast milk instead of cow’s milk in their products, which would have produced a safer  
24 product.

25 63. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically  
26 designed for preterm infants, which contain no cow’s milk. This alternative design provides all the  
27 necessary nutrition for growth and development that cow’s milk-based products provide, without the  
28 same unreasonably dangerous and deadly effects.



64. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the foundation of their products.

**FIRST CAUSE OF ACTION**  
**STRICT LIABILITY FOR DESIGN DEFECT**  
**(Against Abbott and Mead)**

65. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

66. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

67. Abbott and Mead also owed a duty to the consuming public in general, and Plaintiffs in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

68. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infants and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

69. The Injured Infants ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infants outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

70. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

71. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

1 72. Abbott and Mead did not develop a human-milk based product that was safer for premature  
2 infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death,  
3 even though doing so was economically and technologically feasible and even though pasteurized  
4 breast milk was an available alternative.

5 73. Abbott's and/or Mead's products were fed to the Injured Infants, which directly and  
6 proximately caused their NEC and led to injury.

7 74. As a further direct result, Plaintiffs suffered significant emotional distress, loss of income,  
8 and/or other harms. Their lives have been significantly affected by the Injured Infants' injuries.

9  
10 **SECOND CAUSE OF ACTION**  
**STRICT LIABILITY FOR FAILURE TO WARN**  
**(Against Abbott and Mead)**

11 75. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

12 76. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this  
13 litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to provide  
14 adequate warnings or instructions about the dangers and risks associated with the use of their products  
15 with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and  
16 death.

17 77. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and  
18 sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing  
19 their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the  
20 unreasonable risk of harm posed by those ingredients, specifically including the significantly  
21 increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in  
22 this litigation unreasonably dangerous.

23 78. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the  
24 infant products at issue in this litigation because they knew or should have known that their cow's  
25 milk-based premature infant products would be fed to premature infants like the Injured Infants, and  
26 that their products might cause the Injured Infants to develop NEC, severe injury, or death, yet they  
27 failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:  
28

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infants; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infants; and/or
- c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failed to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or
- g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns, like the Plaintiff Parents; and/or
- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

79. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

80. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers' products, the Injured Infants were fed cow's milk-based products, which caused them to develop NEC.

81. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants



1 cow's milk-based formula, they would not have fed the Injured Infants those products. Had the  
2 Plaintiff Parents known of the significant risks of feeding the Injured Infants cow's milk-based  
3 formula, they would not have allowed such products to be fed to the Injured Infants.

4 82. As a further direct result, Plaintiffs suffered significant emotional distress, loss of income,  
5 and/or other harms. Their lives have been significantly affected by the Injured Infants' injuries.

6 **THIRD CAUSE OF ACTION**  
7 **NEGLIGENCE**  
8 **(Against Abbott and Mead)**

8 83. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

9 84. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation,  
10 owed a duty to the consuming public in general, and Plaintiffs in particular, to exercise reasonable  
11 care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm  
12 to users, when such products are used in their intended manner and for their intended purpose.

13 85. At all times relevant to this action, the Injured Infants' healthcare professionals and medical  
14 staff used the products at issue in their intended manner and for their intended purpose.

15 86. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created,  
16 manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based  
17 infant products at issue in this litigation and thereby breached their duty to the general public and  
18 Plaintiffs.

19 87. Specifically, although Abbott and Mead knew or reasonably should have known at the time  
20 of production that their cow's milk-based infant products significantly increased the risk of NEC,  
21 serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty  
22 by:

- 23 a. Failing to warn that cow's milk-based products significantly increase the risk of NEC,  
24 severe injury, and death for the Injured Infants; and/or
- 25 b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for  
26 premature infants like the Injured Infants; and/or
- 27 c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and  
28 provide a false sense of security in that they warn and instruct specifically on certain

1 conditions, but do not warn of the significantly increased risk of NEC and death;  
2 and/or

- 3 d. Failing to insert a large and prominent “black box”-type warning that their cow’s milk-  
4 based products are known to significantly increase the risk of NEC and death when  
5 compared to breast milk in premature infants; and/or  
6 e. Failing to provide well-researched and well-established studies that linked cow’s milk-  
7 based products to NEC and death in premature infants; and/or  
8 f. Failing to insert a warning or instruction to healthcare professionals and other medical  
9 staff in the hospital that parents should be provided information necessary to make an  
10 informed choice about whether to allow their babies to be fed the Defendant  
11 Manufacturers’ products, notwithstanding their substantial risks; and/or  
12 g. Failing to provide a warning in a method reasonably calculated/expected to reach the  
13 parents of newborns, like the Plaintiff Parents; and/or  
14 h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC  
15 in premature infants associated with cow’s milk-based products.

16 88. In addition, although Abbott and Mead knew or reasonably should have known at the time of  
17 production that their cow’s milk-based products significantly increased the risk of NEC, serious  
18 injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing  
19 to perform the necessary process of data collection, detection, assessment, monitoring, prevention,  
20 and reporting or disclosure of adverse outcomes in infants who ingest their products.

21 89. As a direct and proximate result of the Defendant Manufacturers’ failure to act in a reasonably  
22 prudent manner and their breach of duty, the Injured Infants were fed cow’s milk-based products,  
23 which caused them to develop NEC. Had Abbott and Mead satisfied their duties to the consuming  
24 public in general, the Injured Infants would not have been exposed to their unreasonably dangerous  
25 cow’s milk-based products.

26 90. As a further direct result, Plaintiffs suffered significant emotional distress, loss of income,  
27 and/or other harms. Their lives have been significantly affected by the Injured Infants’ injuries.

**FOURTH CAUSE OF ACTION**  
**INTENTIONAL MISREPRESENTATION**  
**(Against Abbott and Mead)**

91. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

92. At all times relevant to this action, the Injured Infants consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

93. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

94. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

95. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infants were fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or



- g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or
- h. That their products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

96. Abbott and Mead knew or reasonably should have known those misrepresentations to be false.

97. The Defendant Manufacturers' misrepresentations were intended to, and in fact did, induce physicians and medical staff, including the Injured Infants' physicians and medical staff, to provide their infant products to babies, including the Injured Infants.

98. The Plaintiff Parents were not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parents to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional misrepresentations, the Injured Infants would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

99. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infants, causing their NEC and subsequent injuries.

100. As a further direct result, the Plaintiff Parents have suffered significant emotional distress, loss of income, and/or other harms. Their lives have been significantly affected by the Injured Infants' injuries.

**FIFTH CAUSE OF ACTION**  
**NEGLIGENT MISREPRESENTATION**  
**(Against Abbott and Mead)**

101. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

1 102. At all times relevant to this action, the Injured Infants consumed the products at issue in their  
2 intended manner and for their intended purpose.

3 103. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation,  
4 owed a duty to the consuming public in general, and Plaintiffs in particular, to provide truthful,  
5 accurate, and complete information about the risks and benefits of using their products when used in  
6 the intended manner and for the intended purpose.

7 104. In the course of their business, Abbott and Mead breached their duty through  
8 misrepresentations made to consumers, physicians, and medical staff in their advertising and  
9 promotional materials, as described in previous paragraphs and incorporated herein, each of whom  
10 were foreseeable recipients of this information.

11 105. Specifically, upon information and belief, Abbott and Mead made the following false  
12 statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infants  
13 were fed their products:

- 14 a. That their cow's milk-based products were safe and beneficial for premature infants  
15 when they knew or should have known that their products were unreasonably  
16 dangerous and cause NEC, serious injury, and death in premature infants; and/or
- 17 b. That their cow's milk-based products were necessary to the growth and nutrition of  
18 premature infants, when they knew or should have known that their products were not  
19 necessary to achieve adequate growth; and/or
- 20 c. That their products have no serious side effects, when they knew or should have known  
21 the contrary to be true; and/or
- 22 d. That cow's milk-based products were safe for premature infants; and/or
- 23 e. That cow's milk-based products were necessary for optimum growth; and/or
- 24 f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- 25 g. That their products were safe and more like breast milk than other infant products and  
26 that they had removed the harmful ingredients of cow's milk when, in fact, the cow's  
27 milk in their products was still capable of causing NEC, serious injury, and death;  
28 and/or

1 h. That their products were based on up-to-date science, which made them safe for  
2 premature infants; and/or

3 i. Omitting the material fact that their products significantly increased the risk of NEC  
4 in premature infants.

5 106. Abbott and Mead were negligent or careless in not determining those representations to be  
6 false.

7 107. The Defendant Manufacturers' misrepresentations were intended to and did in fact induce  
8 physicians and medical staff, including the Injured Infants' physicians and medical staff, to provide  
9 their products to babies, including the Injured Infants.

10 108. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the  
11 Plaintiff Parents to allow their children to be fed Abbott's and Mead's infant products, in justifiable  
12 reliance on all the messaging they received about formula feeding, including, directly or indirectly,  
13 the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent  
14 misrepresentations, the Injured Infants would not have been exposed to their unreasonably dangerous  
15 cow's milk-based products.

16 109. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infants,  
17 causing their NEC and subsequent injuries.

18 110. As a further direct result, Plaintiffs suffered significant emotional distress, loss of income,  
19 and/or other harms. Their lives have been significantly affected by the Injured Infants' injuries.

20 **SIXTH CAUSE OF ACTION**  
21 **NEGLIGENT FAILURE TO WARN**  
**(Against The Hospitals)**

22 111. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

23 112. The Hospitals, as a purchaser, supplier, and/or distributor of the products at issue in this  
24 litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to purchase,  
25 supply, and distribute products that were free of unreasonable risk of harm when used in their intended  
26 manner and for their intended purpose.



1 113. At all times relevant to this action, the Injured Infants used the cow's milk-based products  
2 purchased, supplied, and/or distributed by The Hospitals in their intended manner and for their  
3 intended purpose.

4 114. The Hospitals employed or contracted with the healthcare professionals and medical staff at  
5 the Hospitals, managing these individuals during their treatment of the Injured Infants.

6 115. The Hospitals negligently supplied and distributed the Defendant Manufacturers' milk-based  
7 infant feeding products to these healthcare professionals and medical staff for use on premature  
8 infants, including the Injured Infants.

9 116. Moreover, at all relevant times, The Hospitals knowingly authorized the Defendant  
10 Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at the  
11 The Hospitals Hospitals. The Defendant Manufacturers' sales representatives were encouraged to  
12 interact with The Hospitals' healthcare professionals and medical staff. These interactions provided  
13 the Defendant Manufacturers' sales representatives an opportunity to co-opt The Hospitals'  
14 healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale  
15 of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff  
16 Parents.

17 117. The Hospitals also knowingly allowed the Defendant Manufacturers' sales representatives to  
18 routinely misrepresent the risks and benefits of Defendants' products to The Hospitals' healthcare  
19 professionals and medical staff, including the misrepresentation that premature babies would not  
20 grow adequately with human milk and human milk products and that use of donor milk was not  
21 advised for premature infants.

22 118. The Hospitals knew or reasonably should have known at the time that they acquired,  
23 distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these  
24 products significantly increased the risk of NEC, serious injury, and death.

25 119. Nonetheless, The Hospitals failed to act in a reasonably prudent manner and breached their  
26 duty by:

- 27 a. Failing to warn that cow's milk-based products significantly increase the risk of NEC,  
28 severe injury, and death in those babies; and/or

- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infants; and/or
- c. Failing to warn or instruct their healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or
- d. Failing to provide their healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to The Hospitals' healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

120. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

121. The Hospitals knew or reasonably should have known that their medical professionals and the parents of premature infants, including the Plaintiff Parents, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

122. Had The Hospitals exercised reasonable care by satisfying their duty to warn their medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the

1 Injured Infants would not have been exposed to the Defendant Manufacturers' cow's milk-based  
2 products.

3 123. As a direct and proximate result of The Hospitals' failure to warn of the danger posed by the  
4 Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infants  
5 were fed the Defendant Manufacturers' cow's milk-based products, which caused them to develop  
6 NEC and significant injuries and/or death.

7 124. As a further direct and proximate result of The Hospitals' negligent failure to warn of the  
8 Defendant Manufacturers' unreasonably dangerous products, Plaintiffs suffered significant emotional  
9 distress, loss of income, and/or other harms. Their lives have been significantly affected by the  
10 Injured Infants' injuries.

11 **PRAYER FOR RELIEF**

12 WHEREFORE, Plaintiffs pray for judgment as follows:

13 125. For compensatory damages in an amount to be proven at trial;

14 126. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain  
15 and suffering, mental anguish, and other non-economic losses sustained as a result of Defendants'  
16 conduct;

17 127. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost  
18 profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental  
19 health treatment which have or may be recommended;

20 128. For loss of financial support, services, funeral expenses, companionship, comfort, assistance,  
21 affections, and all other wrongful death damages permitted by law;

22 129. For punitive damages resulting from Defendants' oppressive, fraudulent, and/or malicious  
23 conduct, as permitted by law;

24 130. For interest as permitted by law;

25 131. For attorney's fees, expenses, and recoverable costs incurred in connection with this action;  
26 and

27 132. For such other and further relief as the Court deems proper.  
28



**DEMAND FOR JURY TRIAL**

133. Plaintiffs hereby demand a jury trial for all claims triable.

Dated: April 6, 2022.

Respectfully submitted,

/s/ M. Elizabeth Graham

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